UNITED STATES DISTRICT COURT
DISTRICT OF MINNESOTA

Ruby Foster, and
Kenneth Mager,

Plaintiffs,

Civ. No. 04-135 (RHK/AJB)
MEMORANDUM OPINION AND ORDER

v.

St. Jude Medical, Inc.,

Defendant.

Richard A. Lockridge, Robert K. Shelquist, and Yvonne M. Flaherty, Lockridge Grindal Nauen, PLLP, Minneapolis, Minnesota; and Charles S. Zimmerman and J. Gordon Rudd Jr., Zimmerman Reed, PLLP, Minneapolis, Minnesota, for Plaintiffs.

Tracy J. Van Steenburgh, Halleland Lewis Nilan & Johnson, PA, Minneapolis, Minnesota; and James C. Martin, Reed Smith, Pittsburgh, Pennsylvania, for Defendant.

Introduction

Before the Court is Plaintiffs' Motion For Class Certification. Plaintiffs are individuals who have had one of Defendant's medical products implanted into their hearts during heart bypass surgery. Generally, Plaintiffs allege that they suffered complications as a result of the implantation of Defendant's product. Currently, Plaintiffs have moved to represent a class of persons who also have had one of Defendant's products implanted

into their hearts during heart bypass surgery. For the reasons set forth below, the Court will deny the Motion.[1]

Background

A. The Parties

Plaintiffs Ruby Foster and Kenneth Mager are the named plaintiffs in this case (together, "Plaintiffs"). Foster is a resident and citizen of Memphis, Tennessee. (First Am. Class Action Compl. ("FACAC") ¶ 1.) In March 2002, she underwent a coronary artery bypass graft procedure, otherwise known as a heart bypass surgery, at which time a St. Jude Medical Symmetry Bypass Connector ("Bypass Device") was implanted into her heart. (Id. ¶ 2.) Mager is a resident and citizen of Lake Cormorant, Mississippi. (Id. ¶ 3.) In February 2002, he also underwent bypass surgery at which time a Bypass Device was implanted into his heart. (Id. ¶ 4.) Defendant St. Jude Medical, Inc. is a Minnesota corporation. (Id. ¶ 5.) It designed, manufactured, and marketed the Bypass Device. (Id.)

B. Heart Bypass Surgery and the Bypass Device

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[1] In addition to the Motion For Class Certification, both parties have moved to strike certain expert testimony. (See Doc. Nos. 68, 71, 80.) Generally, the admissibility of expert testimony is governed by Rule 702 of the Federal Rules of Evidence and the factors set forth by Daubert v. Merrell Dow Pharmaceuticals, Inc., 509 U.S. 579, 593-94 (1993) and its progeny. However, the Daubert inquiry is somewhat limited at the class certification stage. See Midwestern Mach. v. Northwest Airlines, Inc., 211 F.R.D. 562, 565-66 (D. Minn. 2001). Given the limited nature of the Daubert inquiry at this point, and given that none of the objected-to testimony was relied upon in resolving the class certification motion, the Court will deny the motions to strike without prejudice. Whether the challenged testimony can withstand Daubert scrutiny is an issue that can be raised at a later stage in the proceedings. See In re Monosodium Glutamate Antitrust Litig., 205 F.R.D. 229, 234-35 (D. Minn. 2001).

Over time, some people develop coronary artery disease, which is a progressive condition caused by the build-up of plaque within the heart's arteries (also known as atherosclerosis). In severe cases, the plaque build-up can restrict the flow of blood and damage heart tissue. Such restrictions in the arteries can produce chest pain, shortness of breath, and fatigue. The restrictions may also result in a heart attack, congestive heart failure, or death.

A heart bypass surgery is performed to improve blood flow through the coronary arteries to the heart muscle. The surgery essentially reroutes, or "bypasses," blood around the clogged arteries. During a bypass surgery, the surgeon removes a portion of a blood vessel from a patient's leg, arm, or chest and then uses that vessel as a conduit to bypass the obstructed coronary artery. After harvesting the bypass vein, the surgeon grafts one end to the aorta, which is the main artery that pumps fresh blood, and grafts the other end to the coronary artery at a point past the obstruction. The suturing of the graft to the aorta and the coronary artery (anastomosis) is usually the most difficult, time consuming, and critical part of the bypass procedure.

Surgeons perform bypass surgery either with or without the aid of a cardiopulmonary bypass machine (heart-lung machine). The majority of bypass surgeries are performed "on-pump," with the heart-lung machine pumping blood during the operation. An "on-pump" procedure allows the surgeon to stop the heart during surgery and clamp off the aorta, thereby maintaining a still, bloodless surgical field to attach the bypass vessel. A minority of bypass surgeries are performed "off-pump," with the

patient's heart continuing to beat. "Off-pump" surgeries are more technically complicated because of the challenges presented with suturing a beating heart.

Traditionally, the suturing is carried out by hand. In May 2001, St. Jude Medical introduced the Bypass Device, which is a mechanical anastomosis device that allows cardiac surgeons to attach the vein grafts to the aorta without suturing or clamping the aorta. Since its introduction, St. Jude's Bypass Device has been implanted approximately 40,000 times. In late 2004, St. Jude discontinued the Bypass Device.

C. Plaintiffs' Complaint

Plaintiffs allege that as a result of the implantation of the Bypass Device they have suffered or are likely to suffer complications, including occlusions (a total blockage of the blood vessel) and stenosis (a narrowing of the blood vessel) of the bypass vein grafts. (See FACAC ¶ 8.) Plaintiffs assert that they and the class members they seek to represent will require ongoing medical surveillance, among other things, due to those alleged complications. (See id. ¶ 9.)

Plaintiffs allege five causes of action: strict liability; breach of implied warranty; breach of express warranty; negligence; and violations of Minnesota's False Advertising Act, Consumer Fraud Act, Unlawful Trade Practices Act, and Uniform Deceptive Trade Practices Act. (See id. ¶¶ 37-70.) Under each cause of action, the following relief is sought:

> (a) an Order pursuant to Rule 23, F.R.C.P. permitting this action to be maintained as a class action as specified herein, appointing Plaintiffs as the representatives of the Class and Plaintiffs' counsel as counsel for the class;

(b) a judgment and/or decree in favor of Plaintiffs and the Class against Defendant creating a trust fund paid for by Defendant which, under Court supervision, will design, pay for and manage the delivery of medical monitoring services, including, but not limited to, testing and preventative screening care of the adverse and latent conditions resulting from, or potentially resulting from, the implantation and use of defective medical products at issue in this suit;

(c) a judgment and/or decree in favor of Plaintiffs and the Class against Defendant creating a trust fund, paid for by Defendant, under Court supervision, to finance medical research on monitoring services, including, but not limited to, testing and preventative screening care of conditions resulting from, or potentially resulting from the defective medical products at issue in this suit;

(d) a judgment and/or order requiring Defendant to bear the cost of publication to members of the Class and the medical community of advising and educating them of the need for appropriate medical screening and monitoring concerning the medical conditions that are at issue in this suit, the content, form and manner of such publication to be approved by the Court;

(e) a judgment in favor of Plaintiffs individually awarding all appropriate compensatory damages for any personal injuries Plaintiffs have suffered or are likely to suffer in the future; and

(f) such further relief as this Court deems necessary, just, and proper.

(FACAC ¶ 44; see id. ¶¶ 52, 58, 65, 70.)

Based on their claims, Plaintiffs seek to certify the following class:

> All persons in the United States and its territories who have had a coronary artery bypass graft procedure utilizing the BYPASS DEVICE manufactured, developed, designed, fabricated, sold, distributed or otherwise placed into the stream of commerce by Defendant, St. Jude Medical, Inc., excepting those who: (a) have already been medically diagnosed with a failure or injury associated with the implanted device to a level or degree that requires or required surgical replacement or repair of all of the BYPASS DEVICES implanted in the person; (b) have died as a result of a failure or injury associated with the implanted device(s); and/or (c) are or were officers, directors and employees (and their immediate family members) of the Defendant.

(FACAC ¶ 11.) Plaintiffs' Motion For Class Certification followed.

Standard of Review

Class certifications are governed by Rule 23 of the Federal Rules of Civil Procedure. The Court may certify a class action only when it is satisfied after "rigorous analysis" that all of Rule 23's prerequisites are met. Lockwood Motors, Inc. v. General Motors Corp., 162 F.R.D. 569, 573 (D. Minn. 1995). Rule 23(a) sets out four threshold prerequisites that must be satisfied before a party can obtain class certification:

> One or more members of a class may sue or be sued as representative parties on behalf of all only if (1) the class is so numerous that joinder of all members is impracticable, (2) there are questions of law or fact common to the class, (3) the claims or defenses of the representative parties are typical of the claims or defenses of the class, and (4) the representative parties will fairly and adequately protect the interests of the class.

Fed. R. Civ. P. 23(a). In addition to the prerequisites of Rule 23(a), the movant must demonstrate that a class action can be maintained under one of the three categories described in Rule 23(b). Fed. R. Civ. P. 23(b).

The party seeking class certification bears the burden of establishing that they have satisfied each of Rule 23's class certification requirements. Coleman v. Watt, 40 F.3d 255, 258 (8th Cir. 1994); Lockwood, 162 F.R.D. at 573. Although a court may not decide the merits of a case at the class certification stage, see Eisen v. Carlisle & Jacquelin, 417 U.S. 156, 177-78 (1974), a motion for class certification "generally involves considerations that are enmeshed in the factual and legal issues comprising the plaintiff's cause of action," Coopers & Lybrand v. Livesay, 437 U.S. 463, 469 (1978) (citations and internal quotations omitted); see Blades v. Monsanto Co., 400 F.3d 562, 566-67 (8th Cir. 2005); Castano v. Am. Tobacco Co., 84 F.3d 734, 744 (5th Cir. 1996). The court ultimately retains broad discretion in determining whether to certify a class under Rule 23. Lockwood, 162 F.R.D. at 573.

Analysis

A. Brief Background On Medical Monitoring

One aspect of Plaintiffs' requested relief is medical monitoring. Medical monitoring claims are a fairly recent development in tort law. Mehl v. Canadian Pacific Ry., Ltd., 227 F.R.D. 505, 516 (D.N.D. 2005.) As described by one court, medical monitoring claims seek "to recover the anticipated costs of long-term diagnostic testing necessary to detect latent diseases that may develop as a result of tortious exposure to toxic substances." Bower v. Westinghouse Elec. Corp., 522 S.E.2d 424, 429 (W. Va. 1999). As noted by another court, medical monitoring has evolved, in part, because the traditional tort system, which was developed to address conflicts raised by simple and

straightforward traumatic injuries, "is ill-designed to deal with the field of mass torts and latent, rather than immediate injuries." Badillo v. Am. Brands, Inc., 16 P.3d 435, 438 (Nev. 2001) (citations omitted). Although recognized by some courts, "the tort of medical monitoring is still novel and considered a non-traditional tort." Thompson v. Am. Tobacco Co., 189 F.R.D. 544, 552 (D. Minn. 1999) (citation omitted).

The states are not uniform in their treatment of medical monitoring claims. Some states treat medical monitoring claims as an independent cause of action. See, e.g., Redland Soccer Club, Inc. v. Dep't of the Army, 696 A.2d 137 (Pa. 1997). Other states recognize medical monitoring claims as a form of damages for an underlying tort, such as negligence or strict liability. See, e.g., Potter v. Firestone Tire & Rubber Co., 863 P.2d 795 (Cal. 1993). Of the states recognizing medical monitoring claims as a independent claim or form of damages, some require a present physical injury, see, e.g., Wood v. Wyeth-Ayerst Labs., 82 S.W.3d 849 (Ky. 2002), while other states do not, see, e.g., Hansen v. Mountain Fuel Supply Co., 858 P.2d 970 (Utah 1993); Ayers v. Jackson Township, 525 A.2d 287 (N.J. 1987). Still other states have not addressed the issue.

B. The Legal Theories, the Relief, and the Class

One of the frustrating aspects of this class certification motion has been trying to determine what legal theories Plaintiffs assert, what relief they seek under those theories, and who makes up the proposed class. Obviously, these are important questions. But after reading Plaintiffs' Complaint, reviewing their memorandum, and listening to their arguments at the motion hearing, the Court is left wanting for consistent arguments.

From the Complaint to the memorandum to the oral argument, the legal theories (or at least their emphasis), the remedies sought (or at least for whom the remedies are sought), and the class make-up have been moving targets.

For example, the Complaint alleges five causes of action. (See FACAC ¶¶ 37-70.) Plaintiffs' memorandum, though thirty-seven pages long, provides very little detail about how these causes of action are certifiable as class claims. The memorandum merely generalizes about each claim, and does not even go so far as to list the elements of any particular cause of action. In short, the memorandum is much like a map that identifies the destination (i.e., the relief) but lacks the directions (i.e., the legal theories). Such a map almost guarantees that one will get lost. Nor did clarity come at oral argument. While the memorandum paid almost no attention to the Minnesota statutory claims, which were asserted in Count V of the Complaint, Plaintiffs' counsel emphasized those claims at oral argument as the basis for class certification nearly to the exclusion of all others. (See Hr'g Tr. at 11, 18-19, 37, 40-41.) Thus, trying to pin down the operative legal theory has been a challenge.

As another example, the Complaint basically seeks two forms of relief. First, a judgment in favor of Plaintiffs and the Class against Defendant creating a trust fund paid for by Defendant which, under Court supervision, will design, pay for and manage the delivery of medical monitoring services. (See, e.g., FACAC ¶ 44(b).) Second, a judgment in favor of Plaintiffs individually awarding all appropriate compensatory damages for personal injuries. (See, e.g., FACAC ¶ 44(e).) Plaintiffs' memorandum

speaks at some length about medical monitoring. (See Mem. in Supp. at 2, 8-9, 19, 23-34.) Very little, however, is said about compensatory damages. Plaintiffs dedicate one footnote to the issue, stating that, "Any resolution of the Class claims would need to preserve the future damage claims for personal injuries that will arise for ten percent or more of the Class members at some time in the future." (Id. at 24 n.3.) At the hearing, Plaintiffs' counsel was asked to explain what relief he was seeking and for whom. In an apparent contradiction of the allegations made in the Complaint, Plaintiffs' counsel responded that he sought medical monitoring and compensatory damages for both the Plaintiffs and the proposed class members. (See Hr'g Tr. at 4-7.) Thus, understanding the relief sought in this case has been a struggle.

Finally, Plaintiffs' description of the class has also been fluid. The Complaint alleges a single, nationwide class of all persons who have had a Bypass Device implanted, except those who have been diagnosed with a failure or injury associated with the device requiring the replacement or repair of the device, who have died as a result of a failure or injury of the device, or who are officers, directors, or employees of St. Jude. (See FACAC ¶ 11.) Plaintiffs' memorandum similarly characterizes the class as "all people in the U.S. who have been implanted with and still have the Symmetry Device except those whose injuries have resulted in their death or the explantation of the valve." (Mem. in Supp. at 2.) At the beginning of the motion hearing, Plaintiffs' counsel stated that the class is comprised of "all people in the United States who have been implanted with and still have a symmetry device in them, who are asymptomatic—that is, either they don't

have an injury or at least just only have a so-called sub-cellular injury. There is no obvious injury." (Hr'g Tr. at 4.) But at the end of the hearing, Plaintiffs' counsel was suggesting all kinds of potential classes—a national class under the Minnesota statutory claims, a medical monitoring class of seventeen states, a national class under strict liability or negligence (although he "acknowledg[ed] fully that that is a more difficult procedure so that should probably be kind of off to the side"), or a class of Minnesota citizens. (See Hr'g Tr. at 41.) Therefore, identifying the class has been difficult.

Ultimately, the constantly changing legal theories, relief, and class composition, contribute to the inescapable conclusion that the class certification motion must be denied. With the foregoing in mind, the Court will begin by assessing Rule 23(a)(4), and will then turn to Rule 23(b)(3) and Rule 23(b)(2).[2]

[2] Of the Rule 23(b) provisions, Plaintiffs argue that class certification is appropriate only under Rule 23(b)(2) and 23(b)(3). (See Mem. in Supp. at 11; Hr'g Tr. at 4.)

C. Rule 23(a)(4)

One precondition for class certification is a finding that "the representative parties will fairly and adequately protect the interests of the class." Fed. R. Civ. P. 23(a)(4). The adequacy inquiry serves to uncover conflicts of interest between the named parties and the class they seek to represent. Amchem Prods., Inc. v. Windsor, 521 U.S. 591, 625 (1997). As one commentator has observed,

> The 'adequacy of representation' requirement was designed to protect the due process rights of absent class members. In a class action, class members who are not named parties to the litigation are nevertheless bound by any judgment in the action. Because the judgment in a class action has claim preclusion (res judicata) implications . . . for the absent class members, due process requires that the interests of absent members be adequately represented by the named class members.

5 James Wm. Moore, Moore's Federal Practice § 23.25[1] (3d ed.) (footnotes omitted). To satisfy the adequacy requirement, Plaintiffs must show "that (1) the representatives and their attorneys are able and willing to prosecute the action competently and vigorously and (2) each representative's interests are sufficiently similar to those of the class that it is unlikely that their goals and viewpoints will diverge." In re Potash Antitrust Litig., 159 F.R.D. 682, 692 (D. Minn. 1995) (citations omitted).

Defendant argues that Plaintiffs do not adequately represent the interests of the class members because they seek only medical monitoring relief for the class, but seek medical monitoring and damages for themselves. (See Mem. in Opp'n at 16-17.) Defendant further asserts that this places the class members at risk of having their damages claims barred by res judicata, and that such a risk makes Plaintiffs inadequate

class representatives. (Id.) This argument raises the issue of what relief is sought and for whom—an issue, as noted above, that lacks a straightforward answer from Plaintiffs. While Plaintiffs' memorandum makes a passing reference to reserving damages claims, and while Plaintiffs' counsel asserted that both Plaintiffs and the proposed class members seek compensatory damages, the Complaint reads differently. It states that the "Plaintiffs individually," in contrast to the class, seek "compensatory damages for any personal injuries Plaintiffs have suffered or are likely to suffer in the future." (See, e.g., FACAC ¶ 44(e)). Therefore, based upon the clear language of the Complaint, the Court finds that compensatory damages are sought only for Plaintiffs, and not for the class members.

It follows that Plaintiffs' efforts to claim compensatory damages only for themselves may, in fact, jeopardize the class members' rights to bring such claims in a subsequent case. See Thompson, 189 F.R.D. at 550; 5 James Wm. Moore, Moore's Federal Practice § 23.25[1] (3d ed.). Res judicata precludes subsequent litigation when certain conditions are met. Thompson, 189 F.R.D. at 550. Under Minnesota law, res judicata principles apply "not only to every matter which was actually litigated, but also as to every matter which might have been litigated, therein." Id. (citing Youngstown Mines Corp. v. Prout, 124 N.W.2d 328, 340 (Minn. 1963)); see Sondel v. Northwest Airlines, Inc., 56 F.3d 934, 938 (8th Cir. 1995) ("[A] judgment on the merits constitutes an absolute bar to a second suit for the same cause of action, and is conclusive between parties and privies, not only as to every other matter which was actually litigated, but also

as to every matter which might have been litigated therein." (quoting Dorso Trailer v. Am. Body & Trailer, 482 N.W.2d 771, 774 (Minn. 1992))).

Given the principles of res judicata, another court may well find that the class members' compensatory damages claims, if any, should have been litigated in this lawsuit. Thompson, 189 F.R.D. at 551; see Reppert v. Marvin Lumber & Cedar Co., 359 F.3d 53, 55-57 (1st Cir. 2004) (finding class settlement under fifty states' consumer protection laws precluded class members' subsequent suit for additional damages under res judicata); Feinstein v. Firestone Tire & Rubber Co., 535 F. Supp. 595, 606-07 (S.D.N.Y. 1982) (finding class representatives "impermissibly split a single cause of action" by asserting only warranty claims on behalf of the class). This possible prejudice to the class members is simply too great for the Court to conclude that Plaintiffs' interests are aligned with those of the class. Thompson, 189 F.R.D. at 551. Accordingly, the Court finds that Plaintiffs have not satisfied Rule 23(a)(4) and this failure precludes class certification. Id.

D. Rule 23(b)(3)

Additional problems for class certification surface upon a consideration of Rule 23(b)(3). Rule 23(b)(3) provides that a class action may be maintained when "questions of law or fact common to the members of the class predominate over any questions affecting only individual members, and that a class action is superior to other available methods for the fair and efficient adjudication of the controversy." Fed. R. Civ. P. 23(b)(3). These considerations seek to cover cases "'in which a class action would

achieve economies of time, effort, and expense, and promote . . . uniformity of decision as to persons similarly situated, without sacrificing procedural fairness or bringing about other undesirable results.'" Amchem, 521 U.S. at 615 (quoting Fed. R. Civ. P. 23 advisory committee's note). Considering these factors, the Court finds that Plaintiffs have not met their burden to demonstrate that common questions predominate or that class resolution is superior.

1. Predominance

In order to make the findings required to certify a class action, the substantive legal issues that will control the outcome of the litigation must be identified. Castano, 84 F.3d at 741. This is especially important when there may be differences in applicable state laws. Id.; see Amchem, 521 U.S. at 624. Plaintiffs have the burden of providing an "extensive analysis" of state law variations to determine whether there are "insuperable obstacles" to class certification. Walsh v. Ford Motor Co., 807 F.2d 1000, 1017 (D.C. Cir. 1986); see Chin v. Chrysler Corp., 182 F.R.D. 448, 453 (D.N.J. 1998). This analysis is required, in part, because "the district court must determine whether variations in state law defeat predominance." Castano, 84 F.3d at 750; see Zinser v. Accufix Research Inst., Inc., 253 F.3d 1180, 1189 (9th Cir. 2001), amended on denial of rehearing by 273 F.3d 1266 (9th Cir. 2001); In re Baycol Prods. Litig., 218 F.R.D. 197, 207 (D. Minn. 2003).

Plaintiffs' counsel admits that he has not done this analysis. When asked why, he responded, "we ran out of room." (Hr'g Tr. at 11.) This wound, however, was entirely

self-inflicted.[3] Because Plaintiffs have not performed an examination of the law, the Court will not engage in a lengthy analysis except to say that a proper consideration of Minnesota's choice-of-law factors reveals that the law of the state where the Bypass Device was implanted would apply to Plaintiffs' negligence, implied warranty, express warranty, and strict liability claims. See Northwest Airlines, Inc. v. Astraea Aviation Servs., Inc., 111 F.3d 1386, 1394-95 (8th Cir. 1997); Nesladek v. Ford Motor Co., 46 F.3d 734, 736-41 (8th Cir. 1995); Nodak Mut. Ins. Co. v. Am. Family Mut. Ins. Co., 604 N.W.2d 91, 93-97 (Minn. 2000); In re Baycol, 218 F.R.D. at 207.

However, the application of the laws of the fifty states makes class treatment of these claims unwarranted. "If more than a few of the laws of the fifty states differ, [courts] would face an impossible task of instructing a jury on the relevant law," making class certification inappropriate. In re Am. Med. Sys., Inc., 75 F.3d 1069, 1085 (6th Cir. 1996); see In re Bridgestone/Firestone Inc., 288 F.3d 1012, 1015-18 (7th Cir. 2002); In re Rhone-Poulenc Rorer Inc., 51 F.3d 1293, 1300-01 (7th Cir. 1995). As alluded to above, claims for medical monitoring are not treated uniformly among the states, and this divergence creates a "myriad of individual legal issues that defeat the predominance requirement" and makes certification "totally unmanageable and inefficient." Zehel-Miller v. Astrazenaca Pharm., LP, 223 F.R.D. 659, 663 (M.D. Fla. 2004). Many states

[3] Although the parties filed a Joint Motion to Expand Page Limits (Doc. No. 38), which was denied (Doc. No. 39), that Motion came only after Plaintiffs had already maxed out the page limits with their opening memorandum (Doc. No. 35).

have not recognized medical monitoring claims, and those which have done so have adopted widely varying criteria for recovery. See In re Rezulin Prods. Liab. Litig., 210 F.R.D. 61, 74 (S.D.N.Y. 2002). Thus, the case has not been made that common issues predominate on the negligence, implied warranty, express warranty, and strict liability claims.

This leaves the Minnesota statutory claims, which were so heavily emphasized by Plaintiffs' counsel at the motion hearing. However, Plaintiffs presented nothing of substance on these claims in their memorandum, which effectively leaves the Court without the benefit of briefing on this issue. As a consequence, the Court is left to decide whether to certify a nationwide class under Minnesota's consumer protection laws based only on Plaintiffs' counsel's sparse argument at the hearing. The Court declines to do so. Simply put, Plaintiffs have not marshaled a persuasive case that common issues predominate on the Minnesota statutory claims. It is noteworthy to add that Plaintiffs' counsel and Defense counsel have recently presented oral argument on this precise issue before the Eighth Circuit in the In re St. Jude Medical Silzone Heart Valve case. Suffice it to say, whether a nationwide class action can be maintained under Minnesota's consumer protection statutes is hotly disputed, but no substantive argument has been made by Plaintiffs here to help resolve the issue in their favor. It is Plaintiffs' burden to persuade the undersigned, and they have not done so.

2. Superiority

In addition, and related to the above determinations, Plaintiffs have not demonstrated that class adjudication is the superior method for the fair and efficient resolution of the dispute. "Under the superiority test of Rule 23(b)(3), a class action must be better than, not merely as good as, other methods of adjudication." 5 James Wm. Moore, Moore's Federal Practice § 23.46[1] (3d ed) (citing cases). Rule 23 identifies four non-exhaustive factors pertinent to the Court's determination of superiority: (1) the interest of members of the class in individually controlling the prosecution or defense of separate actions; (2) the extent and nature of any litigation concerning the controversy already commenced by or against members of the class; (3) the desirability or undesirability of concentrating the litigation of the claims in the particular forum; and (4) the difficulties likely to be encountered in the management of a class action. Fed. R. Civ. P. 23(b)(3).

Plaintiffs devote the following four sentences to their superiority argument:

> A party seeking class certification pursuant to Rule 23(b)(3) must also show 'that a class action is superior to other available methods for the fair and efficient adjudication of the controversy.' This requirement is readily met here. A single class action is undoubtedly superior to thousands of individual actions, with their increased expense, duplication of discovery, and potential for inconsistent results. The efficiencies gained by use of a class action will ultimately benefit all of the class members (as well as St. Jude, though it will oppose class certification) by a dramatic reduction in litigation expenses, and will also conserve valuable judicial resources for other cases.

(Mem. in Supp. at 23.) This is pure hyperbole. The same could be said about any proposed class action; what's lacking is any specificity of how class adjudication is the superior method for this particular case.

In contrast, Defendant argues that a class action is unmanageable. (See Mem. in Opp'n at 30-33.) For one example, it asserts that there is no workable way to determine who the class members are and to give them notice of the class action. (Id. at 30). This argument brings into focus who makes up the class, which is a question, as noted above, to which Plaintiffs have given inconsistent responses. The Complaint alleges a single, nationwide class of all persons who have had a Bypass Device implanted, except those who have been diagnosed with a failure or injury associated with the device requiring the replacement or repair of the device, who have died as a result of a failure or injury of the device, or who are officers, directors, or employees of St. Jude. (See FACAC ¶ 11.) Plaintiffs' memorandum provides a similar definition (see Mem. in Supp. at 2), but their counsel's responses at oral argument, especially at the end of the hearing, paint a different picture (see Hr'g Tr. at 41). Given the clear language of the Complaint, and the similar statements in Plaintiffs' memorandum, however, the Court finds that the proposed class is the nationwide class specified in the Complaint.

"One aspect of manageability is the difficulty and expense of communicating with members of the class, including any practical difficulties and expense of providing mandatory notice of certification and opt out rights to every class member. If the members of the class are not identifiable, managing the action may pose insurmountable

problems." 5 James Wm. Moore, Moore's Federal Practice § 23.46[2][e][i] (3d ed.). In this case, the class would be composed of a single, nationwide class of all persons who have had a Bypass Device implanted, except those who, among other things, have been diagnosed with a failure or injury associated with the device requiring the replacement or repair of the device. (See FACAC ¶ 11.) In the Court's mind, there appears to be some significant challenges in identifying who these people are and distinguishing them from those who have had their Bypass Device replaced or repaired for some other reason. While this difficult determination is at the core of who is in the class and who is not, Plaintiffs provide no satisfactory answer to this critical question. Accordingly, for all the reasons expressed above, the Court concludes that class certification under Rule 23(b)(3) is not appropriate.

E. Rule 23(b)(2)

Finally, the problems identified above make certification under Rule 23(b)(2) unwarranted as well. Rule 23(b)(2) provides that an action may be maintained as a class action if "the party opposing the class has acted or refused to act on grounds generally applicable to the class, thereby making appropriate final injunctive relief or corresponding declaratory relief with respect to the class as a whole." Fed. R. Civ. P. 23(b)(2). While 23(b)(2) class actions have no predominance or superiority requirements, such class actions cannot be certified unless the class is "cohesive." Barnes v. Am. Tobacco Co., 161 F.3d 127, 143 (3d Cir. 1998); see In re Baycol, 218 F.R.D. at 211; Thompson, 189 F.R.D. at 557. There are at least two reasons why courts have recognized a

"cohesiveness" requirement to Rule 23(b)(2) class certifications. First, unnamed class members with valid individual claims are bound by the action without the opportunity to withdraw and may be prejudiced by a negative judgment in the class action. Barnes, 161 F.3d at 143. Second, the suit could become unmanageable and little value would be gained in proceeding as a class action if significant individual issues were to arise consistently. Id. "At base, the (b)(2) class is distinguished from the (b)(3) class by class cohesiveness. . . . Injuries remedied through (b)(2) actions are really group, as opposed to individual injuries." Holmes v. Continental Can Co., 706 F.2d 1144, 1155 (11th Cir. 1983).

In this case, assuming that injunctive relief is sought,[4] the issues that defeat the predominance and superiority requirements of Rule 23(b)(3) also preclude certification under Rule 23(b)(2). See Zehel-Miller, 223 F.R.D. at 664; In re Baycol, 218 F.R.D. at 212-13; In re Rezulin, 210 F.R.D. at 75; Thompson, 189 F.R.D. at 557. Accordingly, the Court concludes that class certification under Rule 23(b)(2) is not appropriate.

[4] This is no small assumption.

F. Conclusion

Having found that Plaintiffs have failed to satisfy Rules 23(a)(4), 23(b)(3), and 23(b)(2), the Court concludes that class certification is not warranted and will deny Plaintiffs' Motion.

Conclusion

Based on the foregoing, and all of the files, records, and proceedings herein **IT IS ORDERED** that:

A. Plaintiffs' Motion For Class Certification (Doc. No. 32) is **DENIED**; and

B. Defendant's Motion to Strike and Objections to the Declaration of Robert A. Phillips Jr. (Doc. No. 68), Plaintiffs' Motion to Strike and Objections to the Declaration of Howard Parker Greisler and Affidavit of Robert F. Wilson (Doc. No. 71), and Defendant's Motion to Strike and Objections to the Declaration of Robert A. Phillips Jr. (Doc. No. 80) are **DENIED WITHOUT PREJUDICE**.

Dated: July 26, 2005

s/Richard H. Kyle
RICHARD H. KYLE
United States District Judge